



The Vitamin Marketing Experts

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March 10, 1998

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING SAW PALMETTO. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING SAW PALMETTO was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"Study after study suggests that *Saw Palmetto* provides important prostate benefits"
"The leading herb benefiting overall prostate health".

Saw Palmetto (latin name: *serenoa repens*), is a low, scrubby palm that grows from South Carolina to Florida and produces a ripe berry. Once known as Sabal, and later Serenoa, it was used in conventional medicine from 1906 to 1950 as a mild diuretic before it fell into oblivion in the U.S. after World War II. Today, studies carried out on over 2,000 patients in Germany confirm the effectiveness of standardized *Saw Palmetto* extract on supporting a healthy prostate especially in middle age and elderly men.

Chemical examination of *Saw Palmetto* reveals that its principal beneficial activity is due to the free fatty acids found in the oil of the berry fruit. Family Essentials™ Today's Man™ contains *Saw Palmetto* that is standardized to have 30% free fatty acid content similar to extracts used in scientific studies.

Very truly yours,
MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs

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STUDIES FOR SAW PALMETTO CLAIMS

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